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What are the requirements for developing a successful national registry of auditory implants? A qualitative study

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ABSTRACT

Objectives Hearing loss is an area of unmet need, and industry is targeting this field with a growing range of surgically implanted hearing devices. Currently, there is no comprehensive UK registry capturing data on these devices; in its absence, it is difficult to monitor clinical and cost-effectiveness and develop national policy. Recognising that developing such a registry faces considerable challenges, it is important to gather opinions from stakeholders and patients. This paper builds on our systematic review on surgical registry development and aims to identify the specific requirements for developing a successful national registry of auditory implants.

Design Qualitative study.

Participants Data were collected in two ways: (1) semistructured interviews with UK professional stakeholders; and (2) focus groups with patients with hearing loss. The interview and focus group schedules were informed by our systematic review on registry development. Data were analysed using directed content analysis. Judges mapped the themes obtained against a conceptual framework developed from our systematic review on registry development. The conceptual framework consisted of five categories for successful registry development: (1) planning, (2) registry governance, (3) registry dataset, (4) anticipating challenges, (5) implementing solutions.

Results Twenty-seven themes emerged from 40 semistructured interviews with professional stakeholders and 18 themes emerged from three patient focus groups. The most important factor for registry success was high rates of data completion. Benefits of developing a successful registry of auditory implants include: strengthening the evidence base and regulation of auditory implants, driving quality and safety improvements, increased transparency, facilitating patient decision-making and informing policy and guidelines development.

Conclusions This study identifies the requirements for developing a successful national registry of auditory implants, benefiting from the involvement of numerous professional stakeholder groups and patients with hearing loss. Our approach may be used internationally to inform successful registry development.

Strengths and limitations of this study

- ► This study adopted an inclusive and robust approach, involving multiple professional stakeholder groups and patients with hearing loss.
- ► Our findings built on a conceptual framework on successful surgical registry development, that was developed following our systematic review and narrative synthesis.
- ► The interview schedules were informed by our published systematic literature review and were piloted and updated before data collection.
- ► Interview and focus group data were extracted and analysed by two independent data judges, with further verification by a data auditor.
- ► We recognise that the use of purposive sampling for identifying professional stakeholders may have been prone to researcher bias.

INTRODUCTION

Hearing loss has been identified as a key public priority by the Department of Health (DoH) and UK policy-makers.[1–3] In the UK, 10 million people suffer from hearing loss, with an estimated annual cost to the economy of £30 billion.[1 4] Hearing loss has a major impact on social functioning and is associated with an increased risk of dementia.[1 5–11] Importantly, the impacts of hearing loss are set to increase with our ageing population.[8 9]

Policy-makers, guideline developers, clinicians, researchers and industry have realised that hearing loss is an area of unmet need.[1 7] This has resulted in increased investment in the development of surgically implanted hearing devices including cochlear implants (CIs), bone conducting hearing devices and middle ear implants.

While auditory implants have been widely adopted, UK registry data on patients with auditory implants are lacking.[2 12–14] Safety incidents around other surgical implants such

as the 'poly implant prostheses' breast implant and the 'metal-on-metal' hip implant highlight the dangers of not collecting such information.[15–17] Conversely, successful registry initiatives such as the National Hip Fracture Database, the National Joint Registry and the National Audit Cardiac Surgery registry highlight the benefits of registry data.[18–20] Hearing stakeholders, policy-makers and patients have recognised that, in the absence of registry data, it is difficult to regulate auditory implants, monitor clinical and cost-effectiveness, and ultimately develop appropriate guidelines and policy.[2]

A potential solution is to develop a national registry of all auditory implants.[2] Recognising that developing such a registry faces considerable challenges, it is important to gather opinions from relevant stakeholders and patients with hearing loss.[21] This paper builds on our recent systematic review[22] on successful surgical registry development and aims to identify the specific requirements for developing a successful national registry of auditory implants.

MATERIALS AND METHODS

Ethical considerations

To facilitate patient attendance, travel expenses were remunerated and gift vouchers were provided.

Data collection

Data were collected in two ways: (1) semistructured interviews with professional stakeholders (PSs); and (2) focus groups (FGs) with patients with hearing loss. The methodological orientation underpinning the study was content analysis,[23] and the study protocol was designed in accordance with the Consolidated criteria for Reporting Qualitative research criteria.[24]

Semistructured interviews with PSs

Participants

We adopted a purposive sampling strategy to identify individuals who were especially knowledgeable about hearing loss and implants.[25] Stakeholders were identified from a network of professionals known to the authors and their collaborators. The list of stakeholders was cross-checked by two independent individuals from separate institutions. At the end of each interview, interviewees were asked to provide contact details of stakeholders with relevant experience to our study. Stakeholders were approached via email invitation. Data analysis commenced after completion of the first interview. Stakeholders were recruited and interviewed until data saturation was reached. PS groups were located across the UK. Information on stakeholder groups can be seen in table 1.

A total of 40 stakeholders were interviewed. This sampling approach led to a response rate of 89%. Reasons for non-participation included: unable to schedule suitable time (n=2) and non-response to invitation (n=3).

Table 1 Stakeholder group frequency

Stakeholder group	n
Audiologists	6
ENT surgeons	9
Non-ENT surgical registry representatives	7
ENT registry leads	3
Industry	4
Registry experts	3
Commissioners	2
Patient charity representatives	2
National guidelines experts	3
Policy experts	3
Health economics experts	2
Department of Health representatives	3
National hearing body representatives	4

ENT, ear, nose and throat.

Procedures

Individual interviews lasted between 14 and 34 min and were digitally recorded and transcribed. Participation was voluntary, and transcripts were anonymised. Participants were interviewed between March 2015 and December 2016, either in person at the University College London (UCL) Ear Institute or via telephone. The semistructured interviews followed an interview schedule comprising 13 questions, each of which contained specific probes (see online supplementary appendix 1). The interview schedule was developed following our narrative systematic review on UK surgical registry development.[22] The interviewer was an ENT Academic Clinical Trainee with expertise in health policy research. The interview schedule focused on (1) opinions on existing auditory implant registries, (2) the requirements of a successful registry and (3) the challenges of establishing a national registry of auditory implants and potential solutions.

The interview schedule was piloted on two professionals and updated following their feedback.

FGs with patients with hearing loss

Participants

Adult patients with hearing loss and their family members were interviewed in three FGs, each comprising 6–7 participants. Participants were identified from a UCL Ear Institute database of patients who had given their consent to take part in clinical research. Participants were approached via email invitation. A total of 19 participants were included. Characteristics of participants are shown in table 2. Ten patients refused to participate due to: lack of time (n=3), caring commitments (n=3) and difficulty in travelling (n=4).

Table 2 Characteristics of participants in focus groups

Patient number	Characteristic	Location
1	Family member of patient with bilateral hearing aids	Birmingham
2	Unilateral CI user	London
3	Family member of patient with unilateral CI	London
4	Unilateral CI and unilateral hearing aid user	Manchester
5	Family member of patient with bilateral hearing aids	Birmingham
6	Bilateral hearing aid user	Leeds
7	Unilateral BAHA user	London
8	Unilateral CI user	Sheffield
9	Bilateral CI user	Oxford
10	Bilateral CI user	Oxford
11	Member of patient group of patients with hearing loss	London
12	Unilateral BAHA user	Leicester
13	Unilateral CI user	Norwich
14	Unilateral CI user and works in a hearing-loss charity	London
15	Unilateral CI and unilateral hearing aid user	London
16	Bilateral BAHA user	London
17	Unilateral BAHA and unilateral hearing aid	Brighton
18	Unilateral CI and unilateral BAHA	Reading
19	Bilateral CI user	Swindon

CI, cochlear implant, BAHA: bone anchored hearing aid.

Procedures

The FGs explored 10 questions, each containing specific probes about a future national registry of auditory implants (see online supplementary appendix 2). The questions were developed from the same systematic review on UK surgical registry development.[22] FGs took place in July 2016 at the UCL Ear Institute and were facilitated by the primary investigator and a patient and public involvement expert.

The FG discussions lasted between 90 and 105 min. The discussions were recorded using a digital recorder and professionally transcribed. Transcripts were anonymised. The FG schedule was trialled on two patients and updated following their feedback.

Analysis

Data analyses were performed in two stages.

Stage 1: two data judges (RM and CT) qualitatively analysed the interview and FG transcripts separately using directed content analysis.[23] Data judges independently read through the interview and FG transcripts and extracted data from the transcripts manually onto separate data extraction tables. The framework of the data extraction tables reflected the structure of the interview and FG schedules. The data judges independently made notes of themes arising from the extracted data and compared their analyses. Discrepancies were discussed and resolved. Amending the themes list was repeated until no new themes emerged. The data judges met periodically with the data auditor (AS) to discuss the analysis.

Stage 2: Judges independently mapped the themes obtained from the stakeholder interviews and FG responses against a conceptual framework developed from our systematic review on registry development.[22] The conceptual framework consisted of five fundamental categories for successful registry development: (1) planning, (2) registry governance, (3) registry dataset, (4) anticipating challenges, (5) implementing solutions.[22] Judges compared their findings, and discrepancies were discussed and resolved.

Patient involvement

- Patients with hearing loss helped inform the research question during previous FGs held at the UCL institute.
- Patients gave feedback on the wording of the FG schedule. Their feedback was used to update the schedule before carrying out the FG discussions.
- Patients were able to suggest the inclusion of their family members in the FGs.
- Results will be disseminated back to study participants during a consensus conference held at the UCL Ear Institute.

RESULTS

Semistructured interviews with PSs

All themes identified are presented below under each interview question. A summary of the extracted data giving rise each theme is provided. Table 3 summarises all themes identified.

PS question (Q) 1: What are your thoughts on the existing auditory implant registries available?

Theme (T) 1a: Existing registries available

Stakeholders were aware of the following UK auditory registries: the Ear Foundation Bone Anchored Hearing Aid registry, The Ear Foundation Bone Conduction Hearing Implant (BCHI) registry, Pochia CI registry, Bawtry Database, Auditbase, National Audit of Bilateral CIs, Auditbase, Otology Web Based database, Cochlear Paediatric Implanted Recipient Observational Study registry. Some implant centres and device manufactures have their own registries.

T1b: Existing registries are limited

Limitations of existing registries include: poor rates of data completion; not user-friendly; difficult to navigate and enter data; overly basic or complex datasets;

Table 3 Themes identified from stakeholder interviews and patient FGs

Semistructured interviews with PSs				
PS Q1. What are your thoughts on the existing auditory implant registries available?	T1a. Existing registries available	T1b. Existing registries are limited		
PS Q2. Do you think a national registry of auditory implants will be of benefit?	T2a. Improve safety and quality of care	T2b. Promote research and innovation	T2c. Facilitate commissioning and guideline development	T2d. Help patient decision-making
PS Q3. What do you think the main purpose or goal of the registry should be?	T3a. To improve the quality and safety of care			
PS Q4. How should the registry be led/who should make the decisions?	T4a. Have steering committee			
PS Q5. How should the registry be managed/maintained?	T5a. Dedicated management team	T5b. Robust IT systems to verify data		
PS Q6. Broadly speaking, what do you think should be included in the dataset?	T6a. Registry dataset	T6b. Quality of life data		
PS Q7. What are the main challenges of establishing a registry?	T7a. 'Buy-in' and data completion	T7b. Resource heavy	T7c. Registry governance	
PS Q8. How can we overcome these challenges?	T8a. Engage with opinion leaders	T8b. Registry development and design	T8c. Make it compulsory	T8d. Make it clearly useful
PS Q9. Should patients be involved in the registry and if so how?	T9a. Leadership and development	T9b. Accessing the registry	T9c. Entering data	
PS Q10. Who should own the data of the registry?	T10a. Independent national body			
PS Q11. How should we fund the registry?	T11a. Multiple sources	T11b. Levy on all implants used		
PS Q12. Should we publish data on specific surgeons and hospitals?	T12a. Wait until the registry is established			
PS Q13. Overall what do you think is the most important factor for making a registry successful?	T13a. Data completeness			
FGs with patients with hearing loss				
FG Q1. What are your thoughts on developing a registry of patients that have surgically implanted hearing devices?	T1a. Improve quality and safety of care	T1b. Help develop national guidelines and policy	T1c. Facilitate patient decision-making	T1d. Challenges to registry development
FG Q2. How do you think patients could be involved in developing, leading or managing such a registry?	T2a. Formal patient representation			
FG Q3. What type of information do you think should be recorded in the registry?	T3a. Registry dataset and easy-to-understand outcome measure			
FG Q4. Would you want to be able to access and add information into the registry?	T4a. Benefits of patient access	T4b. Patients entering data		
FG Q5. How can we help get patients to input their data and be involved in the registry?	T5a. Make the registry useful for patients	T5b. Make the registry simple and use technology	T5c. Inbuilt patient discussion forum	
FG Q6. Would you like the registry to contain information on results of named surgeons or hospitals?	T6a. Inaccurate reflection of practices	T6b. Increase patient choice		
FG Q7. How do you think the data should be protected and kept confidential? Who should be allowed to access your data?	T7a. Data governance	T7b. Data protection committee		
FG Q8. Who should own the data of the registry?	T8a. Independent organisation			
FG Q9. Registries are expensive to set up and maintain. How should the registry be paid for?	T9a. Multiple sources			
FG Q10. Overall, what do you think is the most important factor for making a registry successful?	T10a. Data completeness			

FG, focus group; IT, information technology; PS, professional stakeholder; Q, questions; T, theme.

inappropriate outcome measures; too clinician-focused; unable to sufficiently inform clinical practice, commissioning or guidelines development.

PS Q2: Do you think a national registry of auditory implants will be of benefit?

T2a: improve safety and quality of care

A successful registry would be able to monitor national practices, improve quality of care, identify safety concerns and facilitate implant recall. The registry would also facilitate (inter)national comparison of practices and comparison between implants. Poorly performing centres could be identified and supported. Registry leads noted that their registries were associated with improved clinical standards, shorter waiting times and length of stay, and reductions in morbidity and mortality.

T2b: promote research and innovation

A registry would provide essential data to assess the clinical and cost-effectiveness of auditory implants. It would also facilitate research collaborations, provide data with external validity, refine indications for implantation and drive device improvements and innovations.

T2c: facilitate commissioning and guideline development

A registry would enable monitoring of national clinical activity, facilitating efficient implant procurement, fair distribution of resources and equitable access to care. The registry would also provide valuable information for guidelines and policy development.

T2d: help patient decision-making

A national registry would help patients make informed decisions by providing them with information on procedure effectiveness and risks.

PS Q3: What do you think the main purpose or goal of the registry should be?

T3a: to improve the quality and safety of care

The main purpose of the registry should be to improve the quality and safety of care provided while promoting transparency and patient choice. The registry should also aim to monitor practices and device effectiveness, drive clinical research and assist in the development of policy.

PS Q4: How should the registry be led/who should make the decisions?

T4a: have a steering committee

The registry should be led by an independent steering committee, with representation from: audiologists, an ENT UK representative, implant surgeons, commissioners, policy experts, a health economist, guideline developers, patients and a lay-member. Subcommittees would be responsible for separate areas, including funding, data collection, data verification and governance.

PS Q5: How should the registry be managed/maintained?

T5a: dedicated management team

The registry should be managed by a dedicated management team, responsible for: collecting data centrally, maximising data completion and verifying data. Each hospital should have its own data manager.

T5b: robust information technology systems to verify data

Robust information technology (IT) systems should be in place, to verify and clean data. Registry data can be verified by comparing it with Hospital Episode Statistics data.

PS Q6: Broadly speaking, what do you think should be included in the dataset?

T6a: registry dataset

Table 4 summarises the preoperative, intraoperative and postoperative data-items on which consensus was reached.

Table 4 Stakeholder suggested data-items

Preoperative	Operative	Postoperative
NHS number/patient identifier (linkable to HES)	Name of hospital	Length of stay
Patient demographic details	Name of operation	Hearing test result at each follow-up
Patient diagnosis	Date of surgery	Complications at each follow-up
Indication	Grade of surgeon	Employment status
Primary or revision	Side of surgery	
Cost of implant	Surgery start time	
Hearing test result	Surgical approach	
Comorbidities	Name, make and model of implant	
MDT outcome	Implant serial number	
Employment status	Intraoperative complication(s)	
Date of decision to operate	Surgery end time	
	Cost of implant	

HES, Hospital Episode Statistics; MDT, multidisciplinary team; NHS, National Health Service.

A consensus meeting would be required to establish the specifics of the dataset.

T6b: quality of life data

Quality of life (QoL) data helps provide meaningful outcomes and facilitates health economic analyses. However, it is challenging to reach consensus on QoL outcome measures, and QoL data collection is time consuming and may result in reduced data completion. Therefore, QoL data collection should be introduced when the registry is well established.

PS Q7: What are the main challenges of establishing a registry?

T7a: 'buy-in' and data completion

The main challenge would be achieving long-term 'buy-in' and data completion. Reaching agreement on the registry dataset would also be a key challenge.

T7b: resource heavy

The registry would require considerable financial, human and time resources for initial set-up, data entry and registry maintenance.

T7c: registry governance

Data governance and legal factors are other challenges. These include compliance with data protection and information governance laws, maintaining data security, policing data access, appointing a steering committee, identifying data ownership, acquiring patient consent and ensuring data accuracy and quality.

PS Q8: How can we overcome these challenges?

T8a: engage with opinion leaders

Having opinion leaders as registry advocates would increase registry awareness. Support from influential organisations, such as DoH, the National Institute for Health and Care Excellence (NICE) and commissioning groups, would help maximise registry relevance and funding.

T8b: registry development and design

All stakeholder groups should be involved in registry development, and the registry must be simple, electronic and adaptable to maximise data completion and promote longevity. A minimal dataset should be employed that is quick to complete, with no free-text data entry. Legal, governance and IT experts should be consulted from the outset, with data verification systems in place. A pilot registry would provide user feedback and facilitate registry improvement before national launch.

T8c: make it compulsory

The most effective way to maximise data completion would be by making the registry compulsory for clinician revalidation and for commissioning. Financial incentives could be applied to hospitals, and data completion rates could be published.

T8d: make it clearly useful

Making the registry useful for stakeholders for publications, audits, revalidation, implant procurement and policy development would increase 'buy-in' and data completion. Registry achievements should be disseminated to increase registry awareness.

PS Q9: Should patients be involved in the registry and if so how?

Patients should be involved in the registry in three different capacities.

T9a: leadership and development

A patient representative should be on the steering committee. This would help make the registry more accountable and meaningful.

T9b: accessing the registry

Patients should be given access to the registry, particularly to their own data. This would encourage data accuracy and completion. Safeguards would be needed to comply with data-protection and patient confidentiality.

T9c: entering data

It would be helpful and efficient for patients to enter their own data, particularly QoL data. However, data verification systems would be needed, and patient data entry would be complex and expensive; and should therefore be implemented once the registry is already well established.

PS Q10: Who should own the data of the registry?

T10a: independent national body

The registry should be owned by an independent national body such as: NHS England, DoH, the Secretary of State for Health and Public Health England. These bodies would provide longevity, impartiality, fair access and experience.

PS Q11: How should we fund the registry?

T11a: multiple sources

Funding should be requested from all stakeholder groups. Multiple income streams would provide financial security and increase engagement. Suggested funders included: ENT UK, DoH, patient charities, research grants, National Institute for Health Research, Medical Research Council, Action on Hearing Loss, healthcare providers, industry, The Ear Foundation, British Society of Audiology and The British Academy of Audiology.

T11b: levy on all implants used

A fee, applied to each implant used, would be a helpful source of income. The fee would be paid for by industry and the purchasing hospital.

PS Q12: Should we publish data on specific surgeons and hospitals?

T12a: wait until the registry is established

Potential benefits include: increased patient choice, trust, transparency and promoting a culture of learning. Negatives include: data being misleading if unadjusted for case mix, data poorly reflecting that outcomes are dependent

on the entire healthcare team, reporting bias, risk-averse practices and reduced rates of data completion. Due to these risks, data should be reported once the registry is well established, with robust mechanisms for adjusted reporting.

PS Q13: Overall what do you think is the most important factor for making a registry successful?

T13a: data completeness

High levels of data completion and accuracy are essential. To achieve this, the most important factors include: involving stakeholders and patients during registry development, compulsory data entry, making the registry useful for all groups and having robust data processing systems.

FGs with patients with hearing loss

All themes identified are presented below under each interview question. A summary of the extracted data giving rise each theme is provided. Table 3 summarises all themes identified.

FG Q1: What are your thoughts on developing a registry of patients that have surgically implanted hearing devices?

T1a: improve quality and safety of care

A registry would identify implant problems early, permit recall in the event of safety concerns and allow manufacturers to evaluate their products and improve effectiveness while encouraging competition. It would enable national comparison of outcomes and promote research.

T1b: help develop national guidelines and policy

A national registry would help develop guidance and policy that would reduce variation between centres. It would also help commissioners plan services better, including efficient implant procurement.

T1c: facilitate patient decision-making

By providing accurate information on implant effectiveness, risks and new developments, a registry would help patients make decisions on their care.

T1d: challenges to registry development

Professionals may not input data, resulting in poor rates of data completion, and it would be challenging to reach agreement on the registry dataset and data ownership.

FG Q2: How do you think patients could be involved in developing, leading or managing such a registry?

T2a: formal patient representation

Patients should be formally involved in registry development and leadership. This would make the registry more relevant and useful for patients.

FG Q3: What type of information do you think should be recorded in the registry?

T3a: registry dataset and easy-to-understand outcome measure

There should be a balance between comprehensibility and simplicity: comprehensive datasets would be too time consuming, while basic datasets would provide limited value. Table 5 summarises the data-items on which consensus was reached. The registry should include an outcome measure that is easily understandable by patients.

FG Q4: Would you want to be able to access and add information into the registry?

T4a: benefits of patient access

Patient access would make the registry more patient focused and help patients make decisions on their care.

T4b: patients entering data

Patients were keen to contribute to data entry via 'apps'. Paper-based entry could be used for patients not familiar with online platforms.

Table 5 Patient focus group suggested data-items

Preoperative	Operative	Postoperative
Patient demographics	Name of hospital	Levels of hearing
Occupation	Grade of surgeon	QoL
Comorbidities	Date of surgery	Complications
Preoperative QoL	Indications for surgery	Implant problems
Levels of hearing	Name of implant	Dates of follow-up appointments
Duration of hearing loss	Implant serial number	Details on assistive listening devices
Type of hearing loss	Implant manufacturer	Measure of cognitive status (for elderly patients)
Current hearing devices being used	Duration of surgery	Outcome measure understandable by patients
Information on previous hearing treatments	Intraoperative complication(s)	
Measure of cognitive status (for elderly patients)		

QoL, quality of life.

FG Q5: How can we help get patients to input their data and be involved in the registry?

T5a: make the registry useful for patients

Making the registry useful for patients would increase patient involvement. This could be achieved by having a patient section containing relevant information for patients.

T5b: make the registry simple and use technology

The registry should be simple and easy to use. This could be facilitated by using technology including 'apps' and text message alerts to remind patients to enter data.

T5c: inbuilt patient discussion forum

A patient discussion forum within the registry would help engage patients. This forum would enable patients to learn from one another and share experiences.

FG Q6: Would you like the registry to contain information on results of named surgeons or hospitals?

T6a: inaccurate reflection of practices

Publishing this information may result in inaccurate reflection of practices. Surgeons with complex cases may have a higher risk of complications. Publication may result in surgeons becoming more risk-averse, and this data would not reflect that outcomes are dependent on the entire healthcare team. An independent committee should have access to this data and provide feedback and support where necessary.

T6b: increase patient choice

This information would help increase patient choice and transparency and trust, while giving surgeons incentive to improve practices.

FG Q7: How do you think the data should be protected and kept confidential? Who should be allowed to access your data?

T7a: data governance

Data should be anonymous, with patients identifiable only via a patient number. Patient consent should be obtained for data collection, and registry access should be password protected.

T7b: data protection committee

The registry should have a committee for data protection, with a patient representative. All healthcare professionals should be able to access the registry if necessary for patient care.

FG Q8: Who should own the data of the registry?

T8a: independent organisation

The registry should be owned by an independent body. Registry ownership by a single hospital, academic group or implant company could lead to conflicts of interest, or data manipulation and therefore reduced confidence in the registry.

FG Q9: Registries are expensive to set up and maintain. How should the registry be paid for?

T9a: multiple sources

Funding should be obtained from a mixture of sources, to avoid over-reliance on a single funder. All parties that benefit from the registry should contribute towards it. A fee should be charged for accessing registry data for research or industry purposes.

FG Q10: Overall, what do you think is the most important factor for making a registry successful?

T10a: data completeness

There was consensus among patients that the most important factor for registry success is high levels of data completion. To achieve this, patients and professional groups must be involved during the development and running of the registry.

Organisation of themes into a conceptual framework

The themes obtained from the interviews and FGs were mapped against a conceptual framework, consisting of five fundamental categories for successful registry development[22] (figure 1): (1) *Planning* includes setting registry objectives, appointing a steering committee, establishing registry management systems, acquiring long-term funding and defining registry ownership. (2) *Registry governance* involves appointing a data-protection committee and incorporating patient access and surgeon-specific data reporting once appropriate registry systems are in place. (3) *Registry dataset* includes selecting the fundamental data-items, having a free-text field, holding a dataset consensus meeting and implementing QoL data collection once the registry is well established. (4) *Anticipating challenges* consists of being aware of core challenges, including data completion and reaching consensus on registry dataset, resource requirements, data governance and legal factors. (5) *Implementing solutions* involves putting in place the following strategies to maximise registry success: compulsory data-input, advertise registry benefits, engage with influential groups, involve stakeholders and patients, make the registry user-friendly, have early input from legal, IT and governance experts.

DISCUSSION

Summary of findings

Figure 1 summarises the key requirements for developing a successful national registry of auditory implants.

Relevance to existing research

The call for surgical registries extends beyond auditory implants, with a UK and Europe-wide drive to establish registries for all surgical implants.[26] Across the EU and UK, new implants can enter surgical practice on the basis of similarity to an existing implant, rather than on the basis of its own clinical effectiveness.[26 27] Concerns over the evidence base for surgical implants have been raised by several bodies including the IDEAL collaborative, the EU and the House of Commons Science and Technology

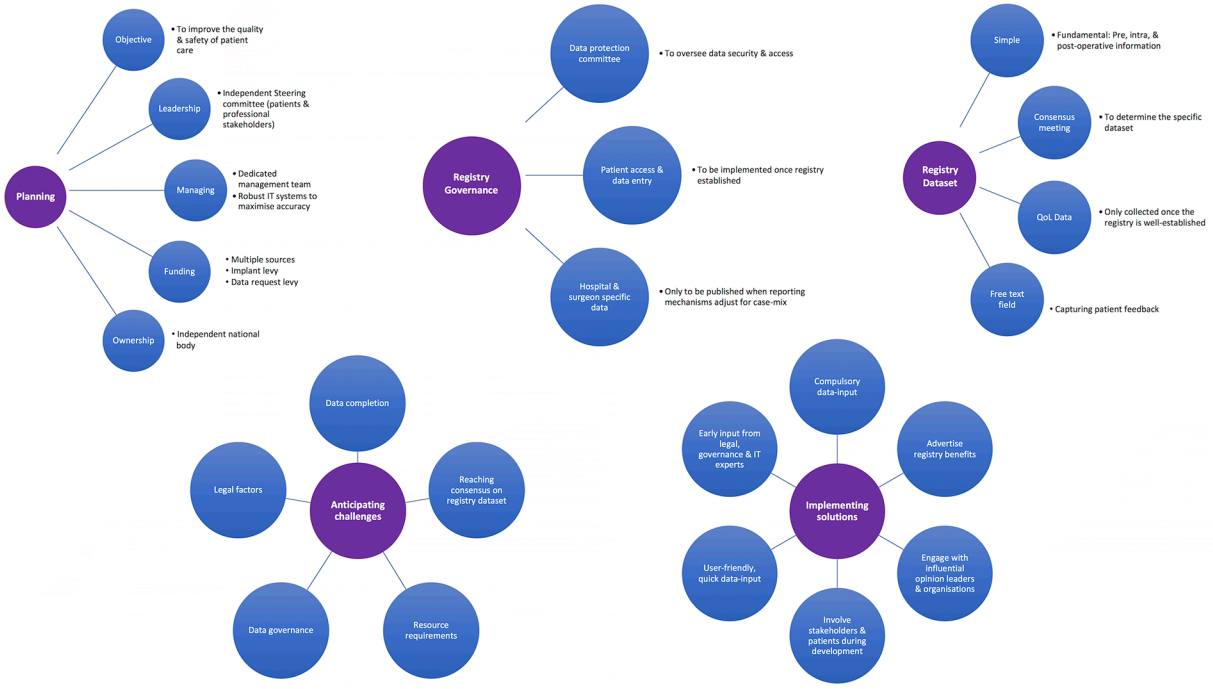

Figure 1 The key requirements for developing a successful national registry of auditory implants.

committee.[26 27] Registries represent a pragmatic approach to address these concerns.[28–33] Unlike conventional clinical studies, registries can answer the fundamental questions required for policy and guideline development, namely: (1) Does it work? (2) Will it work here? (3) Is it worth it?[34] Owing to these factors, the IDEAL collaborative, the DoH, NICE, policy-makers and commissioning groups have called for surgical registries to improve our evidence base, drive quality and safety improvements, and inform policy and guidelines development.[1 13 18 26 27]

Strengths and limitations

A key strength of this study is its inclusive and robust approach, involving multiple stakeholder groups and patients with hearing loss. Moreover, our findings built on a conceptual framework on successful surgical registry development, developed following our systematic review.[22] The approach enabled the collection of a rich dataset in a field where there is a paucity of empirical evidence and a high level of uncertainty. The interview schedules were informed by our published systematic literature review and were piloted before data collection. FGs and interviews were facilitated by individuals with expertise in qualitative interviewing, and patient and public involvement. Data were extracted and analysed by two independent data judges, with further verification by a data auditor. Participants were given an opportunity to discuss any other areas of registry development, not already covered by the questions and follow-ups.

Two limitations may restrict the generalisability of our findings. First, patients were selected from a UCL database of patients, with FGs taking place at the UCL Ear Institute. This resulted in the majority of patients being located in or near London. Second, the use of purposive sampling for identifying PSs may have been prone to researcher bias. However, we attempted to mitigate this limitation by cross-checking the sample with independent experts from external institutions, and by giving all interviewees the opportunity to suggest stakeholders for subsequent interviews.

Implications

This paper identifies the requirements for developing a successful national registry of auditory implants. Its approach and findings can be adopted on an international level to inform successful registry development in other countries.

A successful registry of auditory implants would help develop robust national policy and guidelines. It would also help promote research and innovation, improve healthcare quality and safety and help patients make decisions about their care. From a commissioning perspective, the registry would facilitate equitable access to care and efficient procurement of implants.

CONCLUSION

This study identifies the requirements for developing a successful national registry of auditory implants, benefiting from the involvement of numerous PS groups and patients with hearing loss. Our approach may be used internationally to inform successful registry development.

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